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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,041	02/12/2002	Howard P. Groger	12492.0004-D1	3918
7590 05/04/2004			EXAMINER SODERQUIST, ARLEN	
D. Douglas Price STEPTOE & JOHNSON LLP 1330 Connecticut Avenue, N.W. Washington, DC 20036			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/073,041	Applicant(s) GROGER ET AL.	
	Examiner Arlen Soderquist	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2-12-02, 4-18-02</u> . | 6) <input type="checkbox"/> Other: ____.  |

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1. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. This in reference to copending Application No. 08/553,773 now US Patent 6,521,185.

2. Applicant is advised that should claims 8-10, 12-13 and 16-19 be found allowable, claims 20, 23-26 and 28-31 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Upon consideration of claims 8 and 20, it was determined that both include the same listing of dyes and polymers and the only difference was in the presence of the word "wherein" in line 4 of claim 8.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 34-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Groger (US 6,521,185, hereinafter called Groger'185). In the patent which has an inventorship different from the instant inventorship Groger'185 teaches a method and fluorescent probe based on the affinity of a polymer matrix for an analyte of interest. A highly-sensitive, rapid response fluorescent probe is based on the affinity of a polymer matrix for an analyte of interest. The probe includes a polymer matrix and a dye immobilized in the matrix. The polymer matrix has an affinity for an

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analyte of interest and the dye has little or no sensitivity to the analyte of interest when excited by an excitation source in a free state but has significant sensitivity to the analyte of interest when excited by the excitation source when immobilized in the matrix. Sensors incorporating the polymer/fluorophore probes of the invention have the sensitivity and rapid response needed for detection of chemical agent and biological materials. Sensors using the probes provide sensitivity to Sarin at several hundred parts per trillion in one second or less (they are exposed to the sample and a change in fluorescence is determined in that time frame). A wide-range of near-infrared excitable fluorophores were used as sensitive probes for analytes not detectable when the fluorophores are outside the polymer matrix. The sensors provide early warning of the presence of toxic chemicals, provides for on-line analysis of trace materials in chemical and biological processing operations and biomedical processing operations, and provides for effective biomedical and environmental monitoring. Column 8, lines 29-54, column 12, lines 33-65 and figures 24-25 teach work performed to extend initial screening efforts for incorporating Nile blue 690, quinaldine red, phenosafranin, rhodanile blue, **Oxazine 170**, brilliant crescyl blue, **3,3'-diethylthiatricarbocyanine iodide (DTTC) iodide**, **1,1'3,3,3'-hexamethylindodicarbocyanine iodide (HIDC iodide)**, IR-144 and Methylene Blue in **poly(ethylene maleate)** or poly(vinyl pyridine). (At least the bolded dyes and polymer are instantly claimed in the combination of dyes and polymer found in claim 34.) Dye solutions were prepared to  $10^{-4}$  using either methanol or acetone as solvent. Poly(ethylene maleate) coatings were prepared using 3 ml dye solution containing acetone solvent and 0.1 gram polymer. The excitation and emission spectra were obtained using a SPEX fluorimeter with a xenon lamp source. DMMP vapor was generated by placing approximately 0.0158 g, or 0.0122 ml of liquid DMMP in a heating mantle inside the sample cell and applying current to the heating mantle, resulting in complete vaporization of the drop in 3 to 5 minutes. It is estimated that the polymer/dye probe is exposed to approximately 54 micrograms of material in a 392 cubic centimeter volume. Fluorescence quenching of the polymer/dye probe was measured by comparison of the probe emission in the presence of the vapor to the emission of the probe in the absence of the DMMP vapor. The results of work performed appear in figures 24 and 25.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groger (US 5,577,137, hereinafter called Groger'137) in view of McGill (*CHEMTECH* 1994 hereinafter referred to as McGill '94 or ANTEC'96 hereinafter referred to as McGill '96)), Krech and Dutta, Law or Patonay. Groger '137 teaches a sensor for identification analytes of interest in gases or liquids including one or more dyes placed in a one or more polymer host materials to form an array of sensing materials. Column 1, lines 52-64 teaches that this allows the sensor to specifically identify the analyte of interest. In column 2, line 50 to column 4, line 32 Groger'137 teaches Oxazine 720™ in a polymer (Nafion™) in combination with other dyes Nile Blue A perchlorate™ and Oxazine 750™ in other polymers (polyimide) to form an array for sensing chemical agents including DMMP. Column 4 lines 4-18 teach how the different responses can be used to detect water vapor and how the polymer host improves the signal and sensitivity of a least one of the dyes. Lines 19-25 teach the different fluorescent properties used to detect change in the presence of an analyte including fluorescence amplitude, frequency, decay time, polarization, saturation intensity and stability with temperature. Lines 49-54 recognize that the polymeric materials need to be selected to allow the analyte to contact with the fluorophore. Column 6, lines 19-21 teach that the fluorescence from the material is dependent upon the interaction of the analyte with the fluorophores in the material. Groger'137 does not teach the specific polymers or all of the dyes as claimed.

In the paper McGill '94 discusses choosing polymer coatings for chemical sensors. The purpose of this article was to guide the reader through the various physical and chemical

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processes of selecting sorbent materials as transducer coatings for chemical sensors (pg 27, 4th paragraph). The second paragraph of page 27 teaches that these transducers are found in three general areas: surface acoustic wave devices, fiber-optical devices and electrochemical devices. The third paragraph of page 27 teaches that each of these sensor technologies can employ thin sorbent layers of chemically selective material to collect/concentrate the analyte into the material causing a change in the physicochemical properties of the material for detection by the transducer. The authors were primarily interested in sensors that respond reversibly and recover after the analyte compound was removed. The sorbent materials described here do not form covalent bonds to the analyte vapors, and interactions are ordinarily limited to dispersion, dipolar, and H-bonding interactions. Figure 1 and table 1 show the scope of the polymeric materials used. It is noted that all of the claimed polymeric materials appear to be present in table 1. Table 2 shows the various chemicals tested including DMMP. The scope of this work is limited in application to the analysis of nonionic analyte compounds. Because the authors experience is primarily with SAW chemical sensors, the polymer selection process was described around this sensor format, but the coating selection procedures are equally applicable to the other sensor formats described, and to other technologies where polymer solubility properties are important.

In the paper McGill '96 discusses choosing polymer coatings for gas and liquid chemical microsensors. The sorbent properties of the fourteen polymeric substances listed in table 1 were examined. It is noted that all of the claimed polymers are listed in table 1. The first paragraph under the introduction heading teaches that most chemical microsensors use a thin sorbent polymer coating as an interface between a transducer and a liquid or gas being monitored. The transducer senses some change in the coating material such as an optical property. The paper then presents methods for choosing sorbent polymers that will strongly and selectively sorb an analyte molecule. One example given is the sorption of dimethylmethylphosphonate by the polymer P4V(second full paragraph of page 2082). This paragraph teaches that using polymers having such sensitive responses would have a tremendous advantage in reaching sensor selectivity and sensitivity goals.

In the paper Krech discusses optically sensing chlorinated hydrocarbons with polarity-sensitive dyes in polymeric matrixes. The inclusion of solvatochromic dyes into

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polymeric matrixes was studied for their use in chemical sensing applications. Reichardt's Betaine, 2,6-diphenyl-4-(2,4,6-triphenylpyridinio)phenolate, a polarity-sensitive dye, was incorporated into a variety of polymer films, each representing different polarities and sorbent characteristics. Included in the polymers were the instantly claimed poly(isobutylene), poly(epichlorohydrin) and fluoropolyol. The polymers absorb and concentrate the analyte vapors, thereby influencing the environment surrounding the dye embedded in the polymer. Reversible and reproducible changes in the absorption maximum ( $\lambda_{\max}$ ) of the dye are observed for a series of vapors of different polarities. The observed absorption shift is also influenced by the polymer matrix. Methanol and ethanol vapors produced large blue shifts in  $\lambda_{\max}$  (average ~103 and 63 nm, respectively) for most of the polymer films tested, while isopropanol, acetone, and some chlorinated hydrocarbons produced varying responses in the different films. The variety of responses to the chlorinated hydrocarbons: dichloromethane, chloroform, and  $\text{CCl}_4$  in the different polymer matrixes demonstrate the feasibility of sensor arrays and pattern recognition techniques for the determination of specific chlorinated analytes.

Dutta studied the spectroscopic properties of Nile Red (NR), a highly fluorescent laser dye, in organic solvents, binary solvent mixtures and polymers. Spectroscopic studies revealed remarkable changes in the absorption and emission band positions and intensities as a function of the polarity of the medium. Such large changes have been attributed to the twisted intramolecular charge transfer (TICT) state of the molecule in polar medium. Experimental results show that the molecule is sensitive to the polarity of its microenvironment and is an excellent probe for systems presenting restricted geometries. They incorporated NR into thin films of poly(methyl methacrylate)(PMMA) and poly(vinyl alcohol)(PVA) and found that the micropolarity in PVA is greater than that in PMMA. In PVA, the micropolarity corresponds to that of a binary mixture of acetonitrile and water, whereas in PMMA, the micropolarity corresponds closely to that of pure acetonitrile.

In the paper Law presents the effects of structural changes on the absorption and multiple fluorescence emission of bis[4-(dimethylamino)phenyl]squaraine and its derivatives. The UV and steady state fluorescence of the donor-acceptor-donor (D-A-D) bis[4-(dimethylamino)phenyl]-squaraine (I; R = Me, R1 = H), I (R = Et, Pr, Bu, C18H37; R1 = H, Me, MeO, OH, F, Et), or the analogs II, III, or IV were examined. Compound 12 of table 1 is

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currently being claimed. All substituents on I ( $R = R1 = H$ ) exert bathochromic effects in solution which originate from solute-solvent complexes whose formation constants increase with the D-A-D charge transfer character of I. I have strong red absorptions in solution and are panchromatic in the solid. Temperature and solvent effects, in mixed solvent systems, on the fluorescence show that the observed multiple emission bands (identified from their Stokes shifts) arise from 3 excited states: the free singlet state, the solvent complexed singlet state, and a twisted excited singlet state which is formed, in the radiationless decay (via rotational relaxation), from the other 2 singlets.

In the paper Patonay discusses near-infrared probes for determination of solvent hydrophobicity. The composition of aqueous solvents plays an important role in the spectroscopic characteristics of near-IR (NIR) dyes. The effects of solvent hydrophobicity on NIR spectral characteristics were studied with the use of different NIR dyes. An NIR dye (I) that belongs to the diethylthiacarbo-cyanine family was found to be the most sensitive to changes in the hydrophobicity of the environment. Dye I was used as a model dye to evaluate the analytical utility of this change. In pure water-miscible organic solvents, the absorption maximum for I appears in the region of 807 to 818 nm. If the hydrophobicity of the solvent mixture decreases by an increase in water concentration, an additional, well-separated absorption peak, which can be attributed to the dimer, appears at 698 nm. The relative intensity of these two peaks can be exploited for the determination of the composition of the solvent mixture. The method is evaluated with the use of the polarity parameter (P) for different solvent systems. The described method can be useful for quick spectroscopic determination of P values that are important for several analytical applications, e.g., in spectroscopy or reversed-phase chromatography of the dyes in figure 1, IR-125 dye is the instantly claimed Indocyanine green dye.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the polymers of McGill '94 or McGill '96 as a replacement for the polymer of Groger '137 in the device of Groger '137 because of their known sorption properties for DMMP and the ability of those polymers with a dye incorporated therein to exhibit an optical response to the sorption of an analyte as shown by Krech. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate other dyes known to have polarity or hydrophobicity dependent responses such as taught by Dutta, Law or Patonay into the



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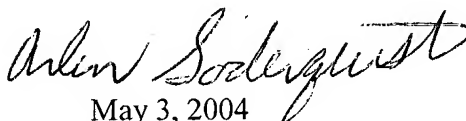
Groger '137 device because of their known response to changes in polarity or hydrophobicity and the expectation that those type of changes can be measured in a polymer dye system as taught by Krech, McGill '94 and McGill '96.

7. The information disclosure statement filed February 12, 2002 does not have a legible copy of each publication listed in either the instant application or the parent application. As a result those publications have been lined through. The additionally cited art was of record in the parent application but not listed in the information disclosure statements filed by applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



May 3, 2004

ARLEN SODERQUIST  
PRIMARY EXAMINER